

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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In re: PAMIDRONATE PRODUCTS	:	
LIABILITY LITIGATION	:	Case No.: 1:09-md-02120-KAM-SMG
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This Document Relates To:	:	
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Case No.: 1:10-cv-01860-KAM-SMG	:	
<i>Bartoli, et al. v. APP Pharmaceuticals, Inc. et al.</i>	:	
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**MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS APP
PHARMACEUTICALS, INC., BEN VENUE LABORATORIES, INC. D/B/A BEDFORD
LABORATORIES, HOSPIRA, INC., SANDOZ INC.,
AND TEVA PARENTERAL MEDICINES, INC.'S
MOTION TO DISMISS ALL REMAINING PLAINTIFFS' CLAIMS**

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**MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS APP
PHARMACEUTICALS, INC., BEN VENUE LABORATORIES, INC. D/B/A BEDFORD
LABORATORIES, HOSPIRA, INC., SANDOZ INC.,
AND TEVA PARENTERAL MEDICINES, INC.'S
MOTION TO DISMISS ALL REMAINING PLAINTIFFS' CLAIMS**

In light of the opinion of the Supreme Court of the United States in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), *reh'g denied*, defendants APP Pharmaceuticals, Inc., Ben Venue Laboratories, Inc. d/b/a Bedford Laboratories, Hospira, Inc., Sandoz Inc., and Teva Parenteral Medicines, Inc. (collectively, "Defendants") move for an Order dismissing the claims of all remaining plaintiffs in this consolidated proceeding, specifically including Jane Clark (a/k/a Hazel Jane Clark), Marjorie McDonald, Christopher Raso (o/b/o Susan Raso), Sylvia Rose, Karen Shareff, Betty Anne Woodard, Carol Strong (successor: Stacy Strong), Skyla Whaley (o/b/o Doris Whaley), and Cynthia Burke (o/b/o Ed Burke) (collectively, "Plaintiffs") pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure. In support of their motion, Defendants state as follows:

PRELIMINARY STATEMENT

Pursuant to the United States Supreme Court's recent decision in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), *reh'g denied*, Plaintiffs' claims must be dismissed because they are preempted by federal law.

On June 23, 2011, the Supreme Court in *Mensing* held clearly, unequivocally, and without exception that state-law tort claims based on any alleged failure to warn of the purported risks of generic medications are preempted by federal law. *See Mensing*, 131 S. Ct. 2567. Plaintiffs' Second Amended Complaint purports to assert causes of action based on Defendants' alleged failure to warn of the purported side effects from use of the generic drug pamidronate. However, Plaintiffs' allegations cannot survive the Supreme Court's clear ruling that federal law

prohibits manufacturers of generic drug products from adding or strengthening product warnings to comply with state-law duties to warn.

PROCEDURAL HISTORY

Plaintiffs filed their Second Amended Complaint (“Complaint”) on January 6, 2011. Defendants then filed a Motion to Dismiss Plaintiffs’ Complaint on April 26, 2011, which Plaintiffs opposed on June 10, 2011. Following the Supreme Court’s *Mensing* decision on June 23, 2011, this Court stayed decision on the pending Motion to Dismiss, while the parties worked to obtain voluntary dismissals of the plaintiffs’ claims against Defendants. Of the plaintiffs included in this multi-plaintiff complaint, 125 plaintiffs voluntarily have dismissed their claims against Defendants. Pursuant to the Court’s November 25, 2011 Order, Defendants were granted permission to file this motion to dismiss the remaining Plaintiffs’ claims.

PLAINTIFFS’ ALLEGATIONS

Plaintiffs’ Complaint purports to assert the following theories of liability against Defendants: Strict Product Liability – Design Defect; Strict Product Liability – Failure to Warn; Negligence; Breach of Express Warranty; and Breach of Implied Warranty. However, no matter how they are worded by Plaintiffs, all Plaintiffs’ theories are based on Defendants’ alleged failure to warn adequately of the purported effects of the use of the generic drug pamidronate.

Plaintiffs’ Complaint is rife with allegations that sound in failure to warn. Plaintiffs’ allegations include the following:

- “Pamidronate as designed, manufactured, labeled and sold by defendants is and was defective due to inadequate warnings because defendants knew or should have known that the product created a risk of harm to consumers.” (Compl. ¶ 37) (Doc. 72.)
- “Pamidronate as designed, manufactured, labeled and sold by defendants was not accompanied by proper warnings regarding possible adverse side effects.” (*Id.* ¶ 42.)

- “As the proximate cause and result of Defendants’ . . . failure to properly warn physicians and consumers, Plaintiffs and/or their decedents . . . were injured.” (*Id.* ¶ 44.)
- “Defendants expressly warranted, by and through statements made by them or their authorized agents, that pamidronate was safe, effective, and fit for its intended uses.” (*Id.* ¶ 52.)

(*See also id.* ¶¶ 24-28, 53-54, 57 (allegations sounding in failure to warn).) Those allegations sound *only* in failure to warn and do not support Plaintiffs’ purported other claims.

The Supreme Court’s decision is dispositive of Plaintiffs’ claims. Accordingly, Defendants respectfully move this Court to enter judgment in their favor.

LEGAL STANDARD

A motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) and a motion for judgment on the pleadings under Rule 12(c) are governed by the same standard. *Hayden v. Paterson*, 594 F.3d 150, 157 n.4 (2d Cir. 2010). A defendant’s Rule 12 motion should be granted when, viewing the facts in the light most favorable to the non-moving party, “unless the allegations are ‘supported by mere conclusory statements,’” the complaint fails to state a claim upon which relief may be granted. *See id.* (quoting *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009); *Burnette v. Carothers*, 192 F.3d 52, 56 (2d Cir. 1999)).

ARGUMENT

I. *Mensing* Requires Dismissal of Inadequate Warning Claims.

This is a clear-cut failure-to-warn case. Plaintiffs’ claims against Defendants are predicated on Defendants’ alleged failure to warn adequately of the purported risks of using pamidronate. In *Mensing*, a case involving the generic drug metoclopramide, the Supreme Court held that generic drug manufacturers cannot change their warnings to respond to plaintiffs’ assertions that they must do just that. 131 S. Ct. 2567.

Claims based upon a failure to warn are preempted because it is impossible to comply with both a state-law duty to strengthen a generic drug's warnings, and the federal mandate that a generic drug's labeling be the same as that of the corresponding brand-name drug:

We find impossibility here. It was not lawful under federal law for the Manufacturers to do what state law required of them. . . .

If the Manufacturers had independently changed their labels to satisfy their state-law duty, they would have violated federal law. Taking [the plaintiffs'] allegations as true, state law imposed on the Manufacturers a duty to attach a safer label to their generic metoclopramide. Federal law, however, demanded that generic drug labels be the same at all times as the corresponding brand-name drug labels. *See, e.g.*, 21 C.F.R. § 314.150(b)(10). **Thus, it was impossible for the Manufacturers to comply with both their state-law duty to change the label and their federal law duty to keep the label the same.**

Mensing, 131 S. Ct. at 2577-78 (emphases added).

The Supreme Court in *Mensing* recognized the case-dispositive impact of its holding. It was unequivocal about the result:

Had [the plaintiffs] taken Reglan, the brand-name drug prescribed by their doctors, *Wyeth v. Levine*, 555 U.S. 555(2009)] would control and their lawsuits would not be pre-empted. But because pharmacists, acting in full accord with state law, substituted generic metoclopramide instead, **federal law pre-empts these lawsuits.** We acknowledge the unfortunate hand that federal drug regulation has dealt [the plaintiffs], **and others similarly situated.**

Mensing, 131 S. Ct. at 2581 (emphases added) (internal citations omitted). Even the dissent was in agreement as to the finality of the Supreme Court's decision for plaintiffs' cases:

First, the majority's pre-emption analysis **strips generic-drug consumers of compensation when they are injured by inadequate warnings.** . . .

As the majority itself admits, a drug consumer's right to compensation for inadequate warnings now turns on the happenstance of whether her pharmacist filled her prescription with a brand-name drug or a generic. If a consumer takes a brand-name drug, she can sue the manufacturer for inadequate warnings under our opinion in *Wyeth*. If, however, she takes a generic drug, as occurs 75 percent of the time, **she has no right to sue.** . . . As a result, in many cases, consumers will have **no ability to preserve their state-law right to recover for injuries caused by inadequate warnings.**

Id. at 2583 (Sotomayor, J., dissenting, joined by Ginsburg, Breyer, & Kagan, JJ.) (emphases added). In short, the Court unanimously recognized that its holding ended all paths to recovery for a generic drug manufacturer's allegedly inadequate warnings. Therefore, Plaintiffs' claims against Defendants based on allegedly inadequate warnings must be dismissed.

II. As Supported by an Overwhelming Number of Post-*Mensing* Decisions, All of Plaintiffs' Claims Are Based on Inadequate Warnings and Therefore Preempted.

Mensing applies to all of Plaintiffs' claims, regardless of how Plaintiffs attempt to characterize them. The breadth of the preemptive sweep of the Supreme Court's decision has been made even more clear by subsequent decisions from the Courts of Appeals. For example, on remand from the Supreme Court, the United States Court of Appeals for the Eighth Circuit declined further briefing and affirmed the district court's judgment of dismissal. *See* Order, *Mensing v. Wyeth, Inc.*, No. 08-3850 (8th Cir. Sept. 29, 2011) (Ex. A); Judgment, *Mensing v. Wyeth, Inc.*, No. 08-3850 (8th Cir. Sept. 29, 2011) (Ex. B). Like this case, *Mensing* involved claims for negligence, strict liability – failure to warn, strict liability – design defect, breach of express warranty, and breach of implied warranty. In its decision, now affirmed by both the Supreme Court and the Eighth Circuit, the *Mensing* district court emphasized that, no matter how the plaintiff categorized her claims, they were all predicated on a failure-to-warn theory:

Plaintiff asserts state-law tort claims against . . . the manufacturers of generic [metoclopramide]. Although Plaintiff has asserted a variety of claims against [the generic defendants], *at the core of all of Plaintiff's claims is the basic assertion that [the generic defendants] failed to adequately warn* about the association between long-term ingestion of [metoclopramide] and movement disorders.

Mensing, 562 F. Supp. 2d 1056, 1058 (D. Minn. 2008) (emphasis added). The court further explained:

Plaintiff alleges that [the generic defendants'] [metoclopramide] labels failed to adequately warn of the risk or prevalence of tardive dyskinesia. In particular, Plaintiff claims that the risk ratio of developing tardive dyskinesia was

significantly higher than the ratio listed on the Reglan and [metoclopramide] labels. . . .

This allegation is at the heart of all of Plaintiff's claims against [the generic defendants]. Thus, all of Plaintiff's claims are essentially "failure to warn" claims and are encompassed by the Court's preemption analysis.

Id. at 1061 & n.6.

Similarly, following the certification of the judgment in *Mensing*, the United States Court of Appeals for the Fifth Circuit vacated the district court's order and remanded the case for entry of judgment in favor of the defendant-appellant, Actavis, Inc. *See Demahy v. Actavis, Inc.*, 650 F.3d 1045 (5th Cir. 2011). On August 30, 2011, consistent with the Fifth Circuit's mandate, the district court entered judgment in favor of Actavis, Inc., and dismissed the plaintiff's suit with prejudice. *See Demahy v. Wyeth, Inc.*, Case No. 08-3616 (E.D. La. Aug. 30, 2011) (Ex. C). Like this case, *Demahy* involved claims for failure to warn, design defect, negligence, and breach of implied warranty.¹

The United States Court of Appeals for the Sixth Circuit also recognized the scope of preemption under *Mensing* in *Smith v. PLIVA, Inc.*, 657 F.3d 420 (6th Cir. Sept. 22, 2011). *Smith* involved three companion cases in which the United States District Court for the Western District of Kentucky² dismissed the plaintiffs' lawsuits against the generic drug defendants as preempted, "finding a conflict between their tort claims and the federal regulation of generic drugs." *Smith*, 657 F. 3d at 422. The cases were fully briefed and argued in the Sixth Circuit before the Supreme Court granted the petitions for writ of certiorari in *PLIVA, Inc. v. Mensing*

¹ In *Demahy*, a case arising under Louisiana law, the plaintiff pled claims under the Louisiana Products Liability Act, which is the sole remedy for alleged products liability-related injuries in Louisiana. *See* Complaint, *Demahy v. Wyeth, Inc.*, No. 08-3616, 2008 U.S. Dist. Ct. Pleadings LEXIS 8107, at *10-25 (E.D. La. 2008). The claims for relief in *Demahy* are, accordingly, not separately denominated as claims for strict products liability, negligence, etc., as in *Mensing*, but are generally based upon the same fundamental theories of liability.

² The other two cases that were part of the appeal were *Wilson v. PLIVA, Inc.*, No. 09-5466 (6th Cir.), and *Morris v. PLIVA, Inc.*, No. 09-5509 (6th Cir.).

and *Actavis, Inc. v. Demahy*. Following the Supreme Court's decision in *Mensing*, the plaintiff-appellants in *Smith* requested and received leave to file supplemental briefing to address the impact of the *Mensing* decision on their claims.

In that supplemental briefing, the plaintiffs argued that “[w]hile the *Mensing* decision alters the theories of liability that [plaintiffs] can pursue, viable causes of action remain against [the generic drug defendants].” Plaintiffs’ Supplemental Brief, *Smith v. PLIVA, Inc.*, No. 09-5460 (6th Cir. Sept. 22, 2011), at 1 (Ex. D). The Sixth Circuit disagreed.

On appeal, the plaintiffs contend that the district court erred in concluding that their state-law failure-to-warn claims against the generic defendants were preempted by federal law. Their arguments must fail, however, given the recent decision of the Supreme Court in *Pliva, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), issued on June 23, 2011. Just as in the present case, the plaintiffs in *Mensing* alleged that their long-term use of generic metoclopramide caused tardive dyskinesia, and they predicated the manufacturers’ liability under state law on the failure to provide adequate warnings on the product’s label. The Supreme Court held unequivocally, however, that federal law preempts state laws that impose on generic-drug manufacturers the duty to change a drug’s label, thus barring the plaintiffs’ state-law tort claims. The plain language of the *Pliva* decision compels the same result here.

See Smith, 657 F. 3d at 423. Like Plaintiffs in this case, the *Smith* plaintiffs had alleged strict liability – failure to warn, strict liability – design defect, negligence, breach of express warranty, and breach of implied warranty. The Sixth Circuit later denied the *Smith* plaintiffs’ petition for a rehearing en banc. *Smith v. Wyeth, Inc.*, Nos. 09-5460, 09-5466, 09-5509 (6th Cir. Nov. 22, 2011) (“[T]he issues raised in the petition were fully considered upon the original submission and decision of the cases.”) (Ex. E).

Since *Mensing*, an overwhelming number of district courts in other cases involving similar causes of action — including in two multi-district litigations— have likewise acknowledged the preemptive effect of the *Mensing* decision and dismissed plaintiffs’ complaints in their entirety. *See In re: Fosamax (Alendronate Sodium) Products Liability*

Litigation (No. II), MDL 2243, Case No. 08-008, 2011 WL 5903623 (D.N.J. Nov. 21, 2011); *In re: Accutane Products Liability (Plevniak)*, MDL 1626 (M.D. Fla. Nov. 9, 2011) (dismissing plaintiffs' claims because "any state-law claim involving a generic drug label or warning is preempted and must be dismissed under *Mensing*") (Ex. F); *Barfield v. Wyeth Inc., et al.*, No. 09-2012 (W.D. La. Jan. 4, 2012) (granting unopposed motion to dismiss based on *Mensing*) (Ex. G); *Fullington v. PLIVA, INC.*, No. 4:10cv000236-JLH, 2011 WL 6153608 (E.D. Ark. Dec. 12, 2011) ("That the holding of *Mensing* encompasses all failure-to-warn claims against generic manufacturers has been recognized in a plethora of subsequent lower court cases that have considered the decision."); *Schrock v. PLIVA USA, Inc.*, No. CIV-08-453-M, 2011 WL 6122768 (W.D. Ok. Dec. 8, 2011); *Whitener v. PLIVA, Inc.*, No. 10-1552, 2011 WL 6056546 (E.D. La. Dec. 6, 2011); *Moretti v. Wyeth, Inc.*, No. 2:08-cv-00396-JCM-CWH (Doc. 282) (D. Nev. Dec. 5, 2011) (court's oral order granting generic manufacturer defendant's motion to dismiss pursuant to *Mensing*); *Stevens v. PLIVA, Inc.*, No. 6:10-0886, 2011 WL 6224556 (W.D. La. Dec. 2, 2011) (judgment adopting magistrate judge's report, in response to unopposed motion, recommending dismissal of all plaintiff's claims as preempted and finding that, even if properly alleged, plaintiff's design defect claim was preempted under the reasoning in *Mensing*); *Gross v. Pfizer, Inc.*, No. 8:10-cv-00110-AW, 2011 WL 5865267 (D. Md. Nov. 22, 2011); *Williamson v. PLIVA, Inc.*, No. 09-736-BAJ-DLD (M.D. La. Nov. 15, 2011) (granting unopposed motion to dismiss based on *Mensing*) (Ex. H); *Guarino v. Wyeth LLC*, No. 8:10-cv-02885, 2011 WL 5358709 (M.D. Fla. Nov. 7, 2011); *Richardson v. Wyeth Inc.*, No. 10-0883, 2011 WL 5402396 (W.D. La. Nov. 7, 2011) (order adopting report and recommendation dismissing plaintiff's lawsuit as preempted); *Waguespack v. PLIVA USA, Inc.*, No. 10-692, 2011 WL 5826015 (E.D. La. Nov. 3, 2011); *Metz v. Wyeth, LLC*, No. 8:10-cv-02658, 2011 WL 5024448 (M.D. Fla. Oct.

20, 2011); *Morris v. Wyeth, Inc.*, No. 3:09-cv-00854, 2011 WL 4973839 (W.D. La. Oct. 19, 2011); *Guilbeau v. Wyeth, Inc.*, No. 09-1652, 2011 WL 4948996 (W.D. La. Oct. 14, 2011) (granting unopposed motion for judgment on the pleadings based on *Mensing* and stating that the allegations in the complaint supported no cause of action other than failure to warn); *Phillips v. Wyeth, Inc.*, No. 10-0882 (W.D. La. Oct. 14, 2011) (Ex. I) (granting unopposed motion for judgment on the pleadings based on *Mensing* for reasons stated in *Guilbeau*); *LaBruyere v. Actavis, Inc.*, No. 2:09-cv-06127 (E.D. La. Oct. 4, 2011) (Ex. J) (granting unopposed motion based on *Mensing*); *Schork v. Baxter Healthcare Corp.*, No. 4:10-cv-00005, 2011 WL 4402602 (S.D. Ind. Sept. 22, 2011); *Beck v. Teva Pharm. Indus. Ltd.*, No. Civ-a-10-1901, 2011 WL 4062219 (E.D. La. Sept. 13, 2011); *Scott v. Baxter Healthcare Corp.*, No. 10-0186, 2011 WL 4007675 (S.D. Ala. Sept. 9, 2011) (granting unopposed summary judgment motion after plaintiff admitted that *Mensing* rendered an argument in opposition “pointless”); *Henderson v. Sun Pharms. Indus. Ltd.*, No. 4:11-CV-0060-HLM, 2011 WL 4015658 (N.D. Ga. Aug. 22, 2011) (denying motion to amend complaint and granting motion to dismiss based on *Mensing* where proposed amended complaint failed to adequately plead factual allegations supporting any cause of action other than failure to warn); *Brown v. Actavis Elizabeth, LLC*, No. 2:10-cv-00011, 2011 U.S. Dist. LEXIS 89393 (E.D. La. Aug. 10, 2011) (holding that, due to *Mensing*, the “suit is meritless and must be dismissed”); *see also Del Valle v. PLIVA, Inc.*, No. 1:11-cv-00113 (S.D. Tex. Dec. 21, 2011) (magistrate’s report and recommendation finding that all of the plaintiff’s claims are failure-to-warn claims and thus barred by *Mensing*) (“Virtually every district court in the country that has examined Reglan/metoclopramide claims, after Mensing, has concluded that the Supreme Court’s decision mandates dismissal of claims against makers of generic drugs for failing to unilaterally include adequate warnings.”) (Ex. K); *Couick v. Wyeth, Inc.*, No. 3:09-cv-

00210 (W.D.N.C. Aug. 12, 2011) (magistrate recommending dismissal in light of *Mensing*) (Ex. L).

Here, as in *Mensing*, *Demahy*, and *Smith*, and these myriad other post-*Mensing* district court cases, each of Plaintiffs' claims – whether characterized as strict liability - design defect, strict liability - failure to warn, negligence, breach of express warranty, or breach of implied warranty – is based upon Plaintiffs' allegations that additional warnings about purported side effects should have been provided to physicians. Each cause of action depends on Plaintiffs' factual allegations that the FDA-required label for pamidronate failed to adequately warn of certain alleged risks. For example, Plaintiffs assert breach of warranty causes of action, which are based upon representations that Defendants allegedly made or failed to make. As to any affirmative representations, Plaintiffs do not identify any statements that Defendants made outside of those contained in the FDA-required label. Claims based on any alleged omissions, regardless of the cause of action, directly conflict with the federal requirement that generic drug labels be the same as brand-name drug labels.

Furthermore, even if Plaintiffs' design defect and other claims were not warnings-based, they still would be subject to dismissal because such claims have been inadequately pled under federal pleading standards. Plaintiffs do no more than improperly provide a “formulaic recitation of the elements of [the] cause of action” and allege no facts to support the design defect claim. *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). The design defect allegations are merely “[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements” and “do not suffice” to state viable causes of action. *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009). A complaint must include factual allegations to support its claims; “‘naked assertion[s]’ devoid of ‘further factual enhancement’” are not sufficient. *Id.* (quoting *Twombly*,

550 U.S. at 557).

The facts asserted in Plaintiffs' Complaint sound only in failure to warn. *See Mensing v. Wyeth, Inc.*, 562 F. Supp. 2d 1056, 1058 (D. Minn. 2008) (finding that "Plaintiff has asserted a variety of claims against [Defendants], [and] at the core of all of Plaintiff's claims is the basic assertion that [Defendants] failed to adequately warn about the association between long-term ingestion of [metoclopramide] and movement disorders" and dismissing the entire complaint as preempted), *rev'd*, 588 F.3d 603 (8th Cir. 2009), *rev'd sub nom. PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011). Thus, *Mensing* precludes all of Plaintiffs' claims.

CONCLUSION

Federal law has long been clear that generic manufacturers cannot unilaterally amend their labeling. Now the Supreme Court has definitively rejected state-law tort claims (like those here) that allege the contrary:

Here, state law imposed a duty on the Manufacturers to take a certain action, and federal law barred them from taking that action. . . . [Plaintiffs'] tort claims are pre-empted.

Mensing, 131 S. Ct. at 2581. That holding applies with full force here and, thus, Plaintiffs' claims are preempted by federal law.

APP Pharmaceuticals, Inc., Ben Venue Laboratories, Inc. d/b/a Bedford Laboratories, Hospira, Inc., Sandoz Inc., and Teva Parenteral Medicines, Inc. therefore respectfully request that this Court grant their Motion to Dismiss and dismiss the claims of any and all remaining plaintiffs in this proceeding.

Dated: January 6, 2012

Respectfully submitted,

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